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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

The National Institute for Occupational Safety and Health (**NIOSH**) of the Centers for Disease Control and Prevention (CDC) Announcement Opportunity for Businesses To Partner With National Institute for Occupational Safety and Health (**NIOSH**) on a Research Project To Evaluate the Reusability of Disposable Filtering Facepiece Respirators (FFR) Used for Protection Against Infectious Aerosols

Authority: 29 U.S.C. Sections 651 et seq.

AGENCY: The National Institute for Occupational Safety and Health (**NIOSH**), Centers for Disease Control and Prevention (CDC).

ACTION: Notice.

SUMMARY: The National Personal Protective Technology Laboratory (NPPTL), **NIOSH**, is conducting research to determine the reusability of filtering facepiece respirators (FFR) exposed to infectious aerosols. One aim of this research is to address whether **NIOSH**-certified FFR are suitable for reuse after decontamination. **NIOSH** proposes to study the effects of decontaminating a diverse array of FFR including **NIOSH**-certified N95, P100, and N95 filtering facepiece respirator/surgical mask. This project will also study the survivability of a simulant influenza virus on FFR. **NIOSH** plans to include in the research study some of the respirator models that have been stockpiled by the U.S government to be used in the event of an influenza pandemic. **NIOSH** also plans to include models that have head straps versus those that do not have head straps, as well as models with and without exhalation valves.

Through this announcement, **NIOSH** is seeking to identify FFR products or prototypes that possess anti-viral or other novel technologies that disinfect or sterilize infectious aerosols (e.g., viruses) as part of their materials of construction. Program funding constraints may limit the number of candidate respirators that may be included in the research program. **NIOSH** will give consideration to the incorporation of novel anti-viral technologies into this research study using the following hierarchy for selection of candidate FFR products and prototypes: (1) The FFR proposed for consideration in this study are commercially available and are currently certified to meeting 42 CFR part 84 requirements, (2) the FFR proposed for consideration is in the process of being certified by **NIOSH** to meet 42 CFR part 84

requirements, (3) the FFR proposed for consideration are either a prototype or a commercially available product that has not been submitted to **NIOSH** for certification and the manufacturer submitting the letter of interest has received **NIOSH** certification for other respiratory protection products, and (4) the FFR prototype contains a unique technology for disinfecting or sterilizing infectious aerosol particles trapped on the exterior surface of the FFR and complements the diversity of technologies already considered in the research design.

Candidate companies will be evaluated based on their capability to achieve the identified criteria in sufficient quantities for testing. Candidates selected could be requested to enter into a Cooperative Research and Development Agreement (CRADA). This announcement does not obligate **NIOSH** to enter into a contractual agreement with any respondents. **NIOSH** reserves the right to establish a partnership based on scientific analysis and capabilities found by way of this announcement or other searches, if determined to be in the best interest of the government.

DATES: Submit letters of interest within 30 days after the date of publication of this notice in the Federal Register.

ADDRESSES: Interested manufacturers should submit a letter of interest with information about their capabilities to: **NIOSH**, National Personal Protection Technology Laboratory, P.O. Box 18070, 626 Cochrans Mill Road, Attn: Jonathan Szalajda, Pittsburgh, PA 15236, E-mail address: zfx1@cdc.gov.

SUPPLEMENTARY INFORMATION: CDC recommends the use of disposable N95, N99, or N100 filtering facepiece particulate respirators (FFR) as the minimum level of respiratory protection against transmission of influenza virus. During a respirator shortage, it is important to consider whether a previously worn FFR can be used again. Reuse guidelines in the **NIOSH** Guide to the Selection and Use of Particulate Respirators Certified under 42 CFR 84 recommend reuse based on loading of the filter and functioning of the respirator. Hospital settings tend to have relatively low concentrations of particulates, but the potential for infectious agents exists. Thus, reuse is more dependent upon infection control procedures than on respirator loading considerations. Respirators exposed to viruses are considered to be potentially harmful because of the possibility for the respirator to act as a fomite and the potential for the viral particle to become dislodged during a sneeze/cough or from rough handling. Thus, respirators worn in the presence of a potentially infected patient or co-worker should be disposed of as infectious waste, and touching of the outside of the respirator should be avoided.

In January, 2006, the Department of Health and Human Services asked the Institute of Medicine (IOM) to convene a committee to conduct an assessment of measures that can be taken that would permit the reuse of disposable N95 particulate filtering respirators in healthcare settings and to report the status of current knowledge about the need and development of reusable N95 respirators for healthcare providers and the general public. Some of the key recommendations from that study were that research studies should be conducted to (1) understand the efficacy of simple decontamination methods that could be used without negative effects on respirator integrity; and (2) understand the risks

associated with handling a respirator that has been used for protection against a viral threat (e.g., study the likelihood that the exterior surface of the respirator might harbor pathogenic microorganisms and thus serve as a fomite).

This research project addresses the major research gaps related to the reusability of filtering facepiece respirators (FFR) during an influenza pandemic. **NIOSH**/NPPTL plans to conduct a variety of tasks in this research project, including: (1) Determining the effect of decontamination on FFR filtration

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performance; (2) Development of a standardized test protocol for measuring the efficacy of a decontamination procedure for FFR; (3) Measure the survivability of a virus simulant trapped on FFR; (4) Measurement of the reaerosolization of a trapped virus simulant on FFR; (5) Assess the efficacy of various decontamination methods suitable for FFR; (6) Determine the effects of decontamination on the FFR fit; and (7) produce a final report that could be used to issue guidance documents on FFR reuse.

FOR FURTHER INFORMATION CONTACT: Jonathan Szalajda, telephone 412-386-6627, or e-mail zfx1@cdc.gov.

Dated: September 19, 2006.
James D. Seligman,
Chief Information Officer, Centers for Disease Control and Prevention.
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